

57778-0006-WO
SMW/AS

PATENT COOPERATION TREATY

DOCKETED TO CPI

From the INTERNATIONAL SEARCHING AUTHORITY

To:
STEVEN M. GIOVANNETTI
PERKINS COIE LLP
P.O. BOX 1208
SEATTLE, WA 98111-1208

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PATENT DOCKETING
DEC 26 2008
PERKINS COIE LLP

PCT 2-22-09
3-22-09

- ☒ Deadline
- ☐ Follow up
- ☐ Previously
- ☐ Abandoned
- ☐ Transferred
- ☐ Docketed

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	
Applicant's or agent's file reference 577788006WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US 08/80362	International filing date (day/month/year) 17 October 2008 (17.10.2008)
Applicant INNOZEN, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

STEVEN M. GIOVANNETTI
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SEATTLE, WA 98111-1208

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PERKINS COIE LLP

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
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(PCT Rule 44.1)

Date of mailing
(day/month/year)

22 DEC 2008

Applicant's or agent's file reference
577788006WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 08/80362

International filing date
(day/month/year) 17 October 2008 (17.10.2008)

Applicant INNOZEN, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

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Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
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For more detailed instructions, see the notes on the accompanying sheet.

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The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

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P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 577788006WO	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> see Form PCT/ISA/220 as well as, where applicable, item 5 below. </div> </div>	
International application No. PCT/US 08/80362	International filing date (<i>day/month/year</i>) 17 October 2008 (17.10.2008)	(Earliest) Priority Date (<i>day/month/year</i>) 19 October 2007 (19.10.2007)
Applicant INNOZEN, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of invention is lacking (see Box No. III).

4. With regard to the title.

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract.

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings.

- a. the figure of the drawings to be published with the abstract is Figure No. _____
- ☐ as suggested by the applicant.
- ☐ as selected by this Authority, because the applicant failed to suggest a figure.
- ☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/80362

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A01N 25/02; A61K 9/12 (2008.04)

USPC - 424/43

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC - 424/43

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC 7 424/43, 435, 439, 440, 46, 466

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST (PGPB, USPT, EPAB, JPAB); Google; Google Scholar

Search Terms Used: thin film, film layer, film strip, composition, active ingredient, effervescent, compound, dissolve, weight ratio, oral cavity, powder matrix, coating, auxiliary composition, absorption agent, flavoring agent, bulking agent, starch, nutritional, ...

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0210810 A1 (Davidson et al.) 21 September 2006 (21.09.2006) ? [abstract], para [0008], para [0012], para [0023], para [0045], para [0033], para [0025], para [0047], para [0043], para [0040], para [0046], para [0056], para [0109], para [0127], para [0019], para [0022], para [0041], para [0027]	1-23, 27, 29-32
Y	US 2001/0006677 A1 (McGinity et al.) 05 July 2001 (05.07.2001) - para [0019]-[0020], para [0057], para [0075]-[0076]	1-23, 29-32
X	US 2007/0087036 A1 (Durschlag et al.) 19 April 2007 (19.04.2007) - para [0039], [abstract], para [0054], para [0033], para [0041], para [0015], [claim 29], para [0012], para [0100]	24-28
Y		17, 19, 21
Y	US 2007/0122455 A1 (Myers et al.) 31 May 2007 (31.05.2007) - para [0105], para [0103], para [0119], para [0124], para [0122]	31-32
A	US 2004/0247649 A1 (Pearce et al.) 09 December 2004 (09.12.2004)	1-32
A	US 2004/0136923 A1 (Davidson) 15 July 2004 (15.07.2004)	1-32

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

08 December 2008 (08.12.2008)

Date of mailing of the international search report

22 DEC 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

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- ☐ Docketed

8-19-09

To: STEVEN M. GIOVANNETTI
PERKINS COIE LLP
P.O. BOX 1208
SEATTLE, WA 98111-1208

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

RECEIVED
INTERNATIONAL SEARCHING AUTHORITY

DEC 26 2008

PERKINS COIE LLP

Date of mailing
(day/month/year)

22 DEC 2008

Applicant's or agent's file reference
577788006WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 08/80362

International filing date (day/month/year)

17 October 2008 (17.10.2008)

Priority date (day/month/year)

19 October 2007 (19.10.2007)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A01N 25/02; A61K 9/12 (2008.04)

USPC - 424/43

Applicant INNOZEN, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

08 December 2008 (08.12.2008)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/80362

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:



the international application in the language in which it was filed.



a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:

a. type of material



a sequence listing



table(s) related to the sequence listing

b. format of material



on paper



in electronic form

c. time of filing/furnishing



contained in the international application as filed



filed together with the international application in electronic form



furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No. .

PCT/US 08/80362

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-32	NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims	None	NO

2. Citations and explanations:

Claims 24-26, and 28 lack an inventive step under PCT Article 33(3) as being obvious over US 2007/0087036 A1 to Durschlag et al. (hereinafter "Durschlag").

As per claim 24, Durschlag teaches an effervescent thin film composition comprising:

- a) a film layer (para [0039]);
- b) a coating applied to at least one side of said film layer ([abstract]), and
- d) an active ingredient (para [0054]).

Although Durschlag does not specifically teach c) wherein the coating comprises at least one effervescent compound, Durschlag does teach compositions with active ingredients containing bicarbonates, and it would have been obvious to one skilled in the ordinary art to use the teachings of Durschlag to obtain the invention as claimed because a skilled artisan would appreciate that bicarbonates can also be used as effervescent agents, and Durschlag allows multiple active ingredients in the edible film compositions.

As per claim 25, Durschlag further teaches wherein an active ingredient is present in the film layer (para [0033]).

As per claim 26, Durschlag further teaches wherein the active ingredient is present in the coating (para [0041] - medicant).

As per claim 28, Durschlag teaches a method of making an effervescent thin film composition comprising: providing a film layer having an active agent incorporated therein (para [0033]), and brushing the powder matrix coating on one or more surfaces of the film layer ([abstract]). Although Durschlag does not specifically teach admixing a powder matrix with an effervescent compound, Durschlag does teach that the powder matrix can contain nutritional supplements including bicarbonates (para [0015], [0041]). It would have been obvious to one skilled in the ordinary art to utilize the teachings of Durschlag to obtain the invention as claimed because a skilled artisan would appreciate that it is known in the art that bicarbonates can be used in compositions to produce an effervescent effect in products.

Claims 1-16, 18, 20, 22-23, 29-30 lack an inventive step under PCT Article 33(3) as being obvious over US 2006/0210610 A1 to Davidson et al. (hereinafter "Davidson") in view of US 2001/0006677 A1 to McGinly et al. (hereinafter "McGinly").

As per claim 1, Davidson teaches a thin film composition for administering an active ingredient ([abstract]) comprising:

- a) a film layer (para [0008]),
- b) wherein the film layer includes at least one active ingredient (para [0012], [0023]);
- c) and a coating applied to at least one side of the film layer (para [0012], [0023]).

However, Davidson does not specifically teach d) wherein the coating comprises at least one effervescent compound.

--See supplemental sheet--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 08/80362

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2 Citations and Explanations:

McGinity teaches effervescent films containing active ingredients that are suitable to be used in pharmaceutical applications (para [0019]-[0020]).

Although Davidson and McGinity do not specifically teach wherein d) wherein the coating comprises at least one effervescent compound, it would have been obvious to one skilled in the ordinary art to combine the teaching of Davidson and effervescent films as taught by McGinity to obtain the invention as claimed because a skilled artisan would appreciate that edible films have been used in different applications to deliver agents, which would include a composition containing an effervescent compound as effervescent compounds could be used in combination with active ingredients as taught by McGinity.

As per claim 2, Davidson further teaches wherein the coating is a powder matrix (para [0008]).

As per claim 3, Davidson further teaches wherein the composition is an edible film strip that rapidly dissolves in an oral cavity and the amount of moisture in the powder matrix is about .001 to 10 wt% (para [0045] - "The dry powder matrix will normally contain a minor amount of retained or bound water or other liquid, typically less than about ten percent by weight.").

As per claim 4, Davidson further teaches wherein the composition dissolves in about 5 to 30 seconds upon contact with the oral cavity (para [0033]).

As per claim 5, Davidson further teaches wherein the film strip weighs about 10 to 80 mg per strip (para [0025] - "A film in accordance with the present invention is generally of a size adapted such that the film is fast dissolving. The weight per strip may vary depending on the application. Generally, the strip may have any effective weight. For human consumption, for example, certain effective weights of the strip include from about 10 to about 400 mg, about 20 to about 200 mg, about 30 to about 100 mg and about 50 mg.").

As per claim 6, Davidson further teaches wherein particle size of the powder matrix is about 10 to 400 mesh (para [0047] - "The size of particulate in the powder matrix can vary as desired, but is preferably in the range of 10 mesh to 400 mesh or finer, preferably 40 mesh to 300 mesh.").

As per claim 7 Davidson further teaches wherein the active ingredient is present in the coating (para [0012]).

As per claim 8, Davidson further teaches further comprising an auxiliary composition selected from the group consisting of a bulking agent (para [0043]).

As per claim 9, Davidson further teaches wherein the film layer comprises a polymer (para [0033]) and the powder matrix coating comprises an absorption agent (para [0040] - auxiliary composition) and a flavoring agent (para [0043]).

As per claim 10, Davidson further teaches wherein the film layer comprises pectin (para [0033]) and the powder matrix comprises starch (para [0040], [0046]).

As per claim 11, Davidson does not specifically teach wherein the absorption agent and a starch are present in a ratio of about 1:1, however, Davidson does teach that the effective weights of film strips and active ingredients included in the films, and that auxiliary compositions can be included in the powder matrix of the film strips to absorb water or saliva (para [0040]). Therefore, it would have been obvious to one skilled in the ordinary to utilize the teachings of Davidson and McGinity to obtain the invention as claimed because a skilled artisan would appreciate that the ratio of the absorption agent to the film layer component would be closer to 1:1 depending on the nature of the active ingredient and other factors such as stability of the film and ease of use. The larger amount of the absorption agent can enable the ability to form a gel whereby the strip can become chewable or slow the release of the active ingredient in the oral cavity or maintain the active ingredient in the oral cavity for a longer duration (para [0040]).

---continued on next supplemental sheet---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/80352

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2 Citations and Explanations:

As per claim 12, McGinly further teaches wherein the flavoring agent gives a flavor of orange (para [0057] . citrus oil).

As per claim 13, Davidson further teaches wherein the active ingredient comprises a pharmaceutical ingredient (para [0056] - "In certain embodiments the compositions and films of the present invention may contain at least one ingredient or agent that is pharmaceutically active.").

As per claim 14, Davidson further teaches wherein the pharmaceutical ingredient is useful for treating diabetic (para [0109] - diabetes agents).

As per claim 15, Davidson further teaches wherein the pharmaceutical ingredient is selected from a group consisting of an active form of tadalafil (para [0127]).

As per claim 16, Davidson further teaches wherein the active ingredient comprises a nutritional supplement (para [0109] . vitamin supplements).

As per claim 18, Davidson further teaches further comprising Vitamin B12 (para [0109] . vitamin B family).

As per claim 20, Davidson further teaches wherein the nutritional supplement is vitamin (para [0109]).

As per claim 22, Davidson further teaches wherein the active ingredient comprises Vitamin C (para [0109]).

As per claim 23, Davidson further teaches wherein the composition is edible (para [0008]) and dissolves in an oral cavity of a subject to which the composition is administered (para [0019]).

As per claim 29, McGinly further teaches effervescent films wherein an alkaline agent causing effervescence such as bicarbonates are incorporated (para [0075]-[0076]), and Davidson further teaches wherein the active ingredient is a stimulant (para [0109]). A skilled artisan would appreciate that sodium bicarbonate can be used as an effervescent compound because bicarbonates can be used as to produce an effervescent effect as taught by McGinly.

As per claim 30, Davidson further teaches wherein the thin film composition is a film strip (para [0022] - "Any effective edible "thin film" or "strip" may be used in accordance with the present invention.").

Claim 27 lacks an inventive step under PCT Article 33(3) as being obvious over Durschlag in view Davidson.

As per claim 27, Durschlag further teaches wherein the coating is a powder matrix (para [0041]. Durschlag does not specifically teach the effervescent compound is sodium bicarbonate, however, Durschlag does teach bicarbonates as part of the composition in the films (para [0015]). A skilled artisan would appreciate that bicarbonates can be used as effervescent agents. However, Durschlag does not specifically teach wherein the active ingredient is a stimulant.

Davidson teaches an edible film containing a powder matrix coating where the active ingredient is a stimulant (para [0109]).

Therefore, it would have been obvious to one skilled in the ordinary art to combine the edible film as taught by Durschlag and the edible film as taught by Davidson to obtain the invention as claimed because a skilled artisan would appreciate that different ingredients and components can be included in the film compositions to provide a therapeutic or beneficial purpose.

Claims 17, 19, and 21 lack an inventive step under PCT Article 33(3) as being obvious over Davidson in view of McGinly and further in view of Durschlag.

As per claim 17, Davidson and McGinly suggest the composition of claim 16. Davidson and McGinly do not specifically teach wherein the active ingredient comprises menthol, pectin, Amica extract, Gymnema sylvestre extract, American Ginseng extract, Ginkgo Biloba extract, cranberry, Guarana extract, however, Durschlag teaches an edible film for delivery of an active ingredient wherein the active ingredient comprises menthol (para [0033]).

Therefore, it would have been obvious to one skilled in the ordinary art to combine the edible film for delivery of active ingredients as taught by Davidson and McGinly and the edible film for delivery of active ingredients as taught by Durschlag to obtain the invention as claimed because a skilled artisan would appreciate that film formulations can contain different ingredients and agents, and the use of a menthol in the film formulation would help said dry coat layer and similar layers are especially effective with low dose active ingredients that require a very low moisture environment to remain stable, as taught by Durschlag (para [0033]).

---continued on next supplemental sheet---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/80362

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V.2 Citations and Explanations:

As per claim 19, Davidson and McGinity suggest the composition of claim 1. Davidson and McGinity do not specifically teach wherein the active ingredient is an electrolyte. Durschlag teaches an edible film for delivery of nutritional supplements including electrolytes ((claim 29); para [0012], [0015]).

Therefore, it would have been obvious to one skilled in the ordinary art to combine the edible film compositions taught by Davidson and McGinity with the edible film composition containing nutritional supplements including electrolytes taught by Durschlag to obtain the invention as claimed because a skilled artisan would appreciate that active ingredients in edible films could include different therapeutic, pharmaceutical, nutritional, and herbal ingredients which would include electrolytes.

As per claim 21, Davidson and McGinity suggest the composition of claim 1. However, Davidson and McGinity do not specifically teach wherein the active ingredients are Vitamin C and Zinc or Calcium and Magnesium. Durschlag teaches edible films wherein the active ingredients are Calcium and Magnesium (para [0100] - "Combination Products--Calcium supplements are available in a dazzling array of combinations with vitamins and other minerals. While vitamin D is necessary for the absorption of calcium, it is not necessary that it be in the calcium supplement (see winter 1998 issue of Osteoporosis Report for information on vitamin D). Minerals such as magnesium and phosphorus also are important, but usually are obtained through food or multivitamins. Most experts recommend that nutrients come from a balanced diet, with multivitamins used to supplement dietary deficiencies."). Therefore, it would have been obvious to one skilled in the ordinary art to combine the edible film containing a powder matrix and coating as taught Davidson and McGinity and the edible film delivering nutritional supplements as taught by Durschlag to obtain the invention as claimed because mineral supplements can be as pharmaceutically active ingredients as taught by Davidson (para [0109]), and a skilled artisan would appreciate that minerals can be included in the films for therapeutic effect.

Claims 31-32 lack an inventive step under PCT Article 33(3) as being obvious over Davidson in view of McGinity and further in view of US 2007/0122455 A1 to Myers et al. (hereinafter "Myers").

As per claim 31, Davidson teaches making and delivering active ingredients in a edible film composition to an individual where dosing is calculated for each strip (para [0027] - "Active ingredients can be delivered in any effective state, including in a solid format, liquid format, or other format, including, for example, gels and pastes. Depending on dose levels, the active ingredients generally can be oil or water soluble. Generally, active ingredients that are stable in aqueous systems are preferred. Active ingredients that are not stable in an aqueous system, however, though not preferred, may still be used. Preferably, the dosage per serving is 1-2 strips but may vary depending on the size of the individual strip and other factors known to one skilled in the art."). Davidson and McGinity do not specifically teach a package of thin film strips according to claim 30, wherein two or more film strips are packaged together without individual packaging or wrapping, wherein the active agents do not bleed or block between the film strips, and the dosage amounts are not skewed.

Myers teaches a package of thin film strips wherein two or more film strips are packaged together without individual packaging or wrapping, wherein the active agents do not bleed or block between the film strips, and the dosage amounts are not skewed (para [0105] - "Anti-tacking agents also may impart reduced film-to-film coefficient of friction, thereby reducing the problem of film dosage units, i.e., strips, adhering to one another. More specifically, in many types of film packaging, strips are stacked against one another. The incorporation of anti-tacking agents may permit the individual strips to slide smoothly against one another as each unit is removed from the packaging."; [0103] - "It is useful to add anti-tacking agents, such as lubricants, antiadherants and glidants to the film compositions of the present invention. Anti-tacking agents assist in the flow characteristics of the material, for example, by reducing sticking to the die in extrusion processes and reducing sticking to the roof of the mouth during administration of the dosage form.").

Therefore, it would have been obvious to one skilled in the ordinary art to combine the edible film strips as taught by Davidson, the effervescent film composition as taught by McGinity, and the packaging of thin film strips with anti-tacking agents used to prevent film strips from sticking to one another as taught by Myers to obtain the invention as claimed because edible film strips had a problem of adhering to each other causing non-uniformity of doses and other consequences, and there was a need to improve the packaging of film strips so that a user can get a uniform dosage out of each film strip and providing ease of use.

---continued on next supplemental sheet---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 08/80362

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.2 Citations and Explanations:

As per claim 32, Myers further teaches a package of thin film strips according to claim 31, wherein each film strip comprises plasticizers (para [0119]) in a film layer in an amount ranging from about 10% to about 15 % on a dry weight basis (para [0124]) - "Further examples of additives are plasticizers which include polyalkylene oxides, such as polyethylene glycols, polypropylene glycols, polyethylene-propylene glycols, organic plasticizers with low molecular weights, such as glycerol, glycerol monoacetate, diacetate or triacetate, triacetin, polysorbate, cetyl alcohol, propylene glycol, sorbitol, sodium diethylsulfosuccinate, triethyl citrate, tributyl citrate, and the like, added in concentrations ranging from about 0.5% to about 30%, and desirably ranging from about 0.5% to about 20% based on the weight of the polymer."; [0122] - "Such extenders may optionally be added in any desired amount desirably within the range of up to about 80%, desirably about 3% to 50% and more desirably within the range of 3% to 20% based on the weight of all components.").

Claims 1-32 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.